REMARKS

Claims 1-26 are pending in this application. Claims 11-18 and 24-26 are withdrawn as being drawn to a non-elected invention, and Claims 1-10 and 19-23 are rejected. By the present amendment, claims 2, 11-18, and 24-26 are hereby canceled without prejudice or disclaimer. Claims 1, 3, 4, 6, 7, 9, 10, and 19-23 are hereby amended. New claims 27-36 are hereby added. Support for the amendment which recites that the predetermined final diameter is the desired diameter of the stent following expansion at a target site in the lumen of a duct, blood vessel, or tube of a mammalian subject is found in paragraphs 13, 17, 35, and 46 and elsewhere in the application. Support for the amendment that the Tg of the polymer is at least 45°C or at least 57°C is found in paragraphs 11 and 24 of the application. Support for the amendment that the stent or device exhibits substantially no negative recoil when expanded mechanically by inflation of the balloon catheter in the lumen of a duct, tube, or blood vessel of a mammalian subject or when expanded mechanically by inflation of the balloon catheter and stored at 37°C for 4 weeks or more is found in paragraphs 8, 13, 22, 33, and 35 and elsewhere in the application. New claims 27-32 are supported by paragraph 24. New claims 33-36 are supported by paragraphs 14 and 46. Accordingly, the amendments and new claims add no new matter.

In view of the amendments and following remarks, applicants respectfully request reconsideration of claims 1, 3-10, and 19-23, and consideration of new claims 27-36.

CLAIM REJECTIONS-35 USC §102

Claims 7-9 and 22-23 are rejected under 35 USC §102(b) as being anticipated by Lafont et al. (US Patent No. 5,957,975)(hereinafter "Lafont et al.")

In order to anticipate claims 7-9, Lafont et al., must disclose not only each and every step recited in claim 7 but also the same order of steps recited in claim 7. In claim 7, step (f), i.e., the sixth step in the claimed method, involves mounting a cylindrical device on inflatable balloon. Although Lafont et al. recites mounting a cylindrical polymeric device on an inflatable balloon, Lafont et al., at a minimum, does not disclose performing steps (b)-(d) of the method recited in claim 7 **before** the polymeric cylindrical device is mounted on an inflatable balloon catheter. In other words, Lafont et al. does not disclose heating the device while expanding it to the final predetermined diameter (as recited in step (b)) **before** the device is mounted on an inflatable

balloon. Moreover, Lafont et al does not disclose mounting the expanded device on a solid support for maintaining the device at the expanded diameter (as recited in step (c)) **before** the device is mounted on the balloon catheter. Nor does Lafont et al. disclose heating the expanded device to a temperature sufficient to erase the polymeric device's memory of the prior processing steps while it is mounted on the solid support (as recited in step (d)) **before** the device is mounted on the inflatable balloon catheter. In addition, Lafont et al. does not disclose rapidly cooling the expanded polymeric cylindrical device at a temperature below the Tg of the polymer to quench the polymeric cylindrical device and to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter of the expanded stent (as recited in step (e)) **before** the device is mounted on a balloon catheter. In column 8, lines 20, Lafont et al. recites a single heating step (which according to Lafont et al. "renders the stent more malleable") before the stent is mounted on a balloon. Lafont et al recites a single cooling step before the device is mounted on a balloon catheter. However, such step does not provide an educated polymeric cylindrical device having a memory of the final predetermined diameter, i.e., the diameter of the expanded stent. Instead, "[s]uch procedure gives the polymeric stent a first memory of this reduced diameter configuration which aids in keeping the stent on the balloon." (See col. 9, lines 32-35 of Lafont et al. Emphasis added.) Lacking a disclosure of a method which involves performing steps (b)-(e) prior to the step of mounting the polymeric device on a balloon catheter, Lafont et al. does not anticipate independent claim 7 or the claims that depend therefrom, i.e., claims 8 and 9.

Claim 22 is directed at a method of preparing a stent that subsequently will be mounted on a balloon catheter and inserted into the lumen of a tube duct of a mammalian subject. Accordingly, claim 22 has been amended for clarity to recite that the method involves multiple steps that are performed before the stent is mounted on a balloon catheter. Step (b) of instant claim 22 involves heating the polymeric cylindrical device to a temperature close to or above the Tg of the polymer while expanding the device to the final predetermined diameter,(i.e. the diameter after the device has been inserted into the lumen of a blood vessel, etc. of the subject and expanded by inflation of a balloon catheter on which it is mounted.). Step (c) of instant claim 22 involves mounting the expanded device on a support for maintaining the device at the final predetermined diameter. Step (d) involves heating the expanded cylindrical device to a

temperature sufficiently above the glass transition temperature (Tg) of the polymer and for a time sufficient to erase memory of previous processing of the polymeric device; and step (e) involves rapidly cooling the expanded polymeric cylindrical device at a temperature below the Tg of the polymer to quench the polymeric cylindrical device and to provide an educated polymeric cylindrical device. At a minimum, Lafont et al. does not disclose performing any of these steps before the stent is mounted on a balloon cathether. At one point, Lafont et al. recites heating the stent prior to expanding it. However, such heating step occurs after the stent is mounted on the balloon catheter and while it is positioned at the target site in the subject. (See column 9, lines 16-19 of Lafont et al.) Accordingly, Lafont et al. does not anticipate claim 22 as amended. Claim 23 depends from claim 22, and for the same reason, is not anticipated by Lafont et al.

CLAIM REJECTIONS-35 USC §103

Claims 1-6 and 19-21 are rejected under 35 USC §103(a) as being unpatentable over Kawai et al., US Patent No. 4,950,258 in view of Lafont et al.

Claims 1 and 19 have been amended to clarify that the claimed methods provide a cylindrical polymeric device (or stent) that is substantially resistant to negative recoil when expanded mechanically (i.e., by inflation of a balloon catheter on which the device/stent is mounted) to a final predetermined diameter, the final predetermined diameter being substatially the same as the desired diameter following expansion of the device/stent at a target site in the lumen of a duct, tube, or blood vessel in a human subject. Kawai et al. does not teach or suggest such a method. Instead, Kawai et al. recites methods in which a polymer that has been molded into a desired shape, heated to memorize the shape, and deformed to another shape by heat-softening "can recover exactly or approximately the initially memorized shape upon heating again." (See col. 2, lines 26-29 of Kawai et al.; See also col. 3, lines 59-62 of Kawai et al. "The, thus prepared molded articles automatically recover their originally memorized or nearly-so shapes on heating at a prescribed temperature."(Emphasis added.)) Indeed, Kawai et al. suggests that better "shape recovery" is achieved at higher temperatures. (See col. 7, lines 52-53 of Kawai et al. "The results show that the higher the temperature for shape recovery, the quicker the recovery occurs...") Nowhere in Kawai et al. is there any suggestion that a polymeric cylindrical device that has been treated as recited in claims 1 and 19 of the present application could be

returned to the final predetermined diameter simply by expanding the balloon catheter on which it is mounted. Moreover, and perhaps more importantly, there is no suggestion or teaching in Kawai et al. that a cylindrical device having a final predetermined diameter which is treated as recited in steps (a)-(c) of claims 1 and 19 of the instant application and then heated and crimped to a reduced diameter and then expanded to the final predetermined diameter by application of mechanical force alone* would maintain such an expanded diameter for any period of time when implanted in the lumen of a duct, blood vessel or stored at 37°C for 4 weeks or more as recited in claims 1 and 19 of the instant application. Accordingly, Kawai et al. does not render obvious the methods of claims 1 and 19, or any of the claims that depend therefrom.

Lafont et al. does not provide the teachings or suggestions that are missing from Kawai et al. In other words, Lafont et al. does not teach or suggest that devices prepared in accordance with the methods recited in claims 1 and 19 and expanded to the final predetermined diameter simply by inflating the balloon on which they are mounted are substantially resistant to negative recoil. Indeed, Lafont et al. specifically recites that the implanted stent, which is already mounted on the balloon catheter, and therefore at a reduced diameter, is "heated to a temperature greater than the glass transition temperature of the polymers used to form the stent" before it is expanded by inflation of the balloon (See col. 9, lines 16 to 19 of Lafont et al. Emphasis added) Thus, even when Lafont et al. is combined with Kawai et al., one of ordinary skill in the art still could not reasonably predict that the methods recited in claims 1 and 19 would produce a stent that is resistant to negative recoil when expanded mechanically (and without heating) and implanted in a duct, tube, or vessel in a mammalian subject or stored at 37°C for 4 weeks or more. Accordingly, Kawai et al and Lafont et al, either alone or combined, do not render any of the claims in the instant application obvious.

* In paragraph 35 of the instant application, applicants recite that the polymeric device/stent can be expanded to the final predetermined diameter by inflation of the balloon catheter OR OPTIONALLY by heating the polymeric device/stent to a temperature above body temperature during inflation of the balloon to assist in this mechanical expansion. Thus, in accordance with the present method, it is not necessary to heat a device which is at a reduced diameter to provide a device that recovers and maintains the "expanded" final predetermined diameter.

Applicants submit that claims 1, 3-10, and 19-23 and new claims 27-36. are now in condition for allowance. Prompt notice of such allowance is respectfully requested. If the Examiner has any questions regarding the claims, he is encouraged to contact the undersigned at the phone number listed below.

Respectfully submitted,

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By: Pamela A. Docherty

Pamela A. Docherty, Reg. No. 40,591
(216) 622-8416